

# CHAI HIV MID-YEAR MARKET MEMO, 2017



Highlighting the latest trends in HIV treatment, diagnostics, and prevention

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Questions about the HIV Mid-Year Market Memo? Please feel free to reach out to [Vineet Prabhu](#)

## Introduction

Introducing the first edition of CHAI's HIV Mid-Year Market Memo, an informational brief that covers the latest trends in the HIV space in low- and middle-income countries (LMICs) since the publication of CHAI's annual [ARV Market Report](#) in October 2016. For further background on these topics, please see the above report



### Data Sources For The Memo:

- 1 CHAI's Annual Data Request to 20+ LMICs  
*Benin, Brazil, Cambodia, Cameroon, Ethiopia, India, Indonesia, Kenya, Laos, Lesotho, Malawi, Mozambique, Myanmar, Nigeria, Senegal, South Africa, Swaziland, Tanzania, Togo, Uganda, Vietnam, Zambia, and Zimbabwe*
- 2 Articles from journals and news outlets
- 3 Supplier and partner market intelligence
- 4 Major conferences and meetings

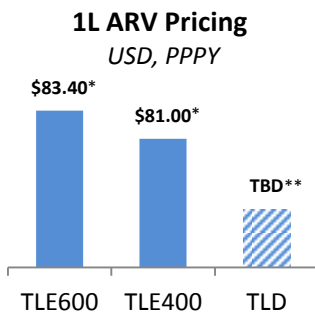
#### Acronyms Used

<b>3TC:</b> lamivudine	<b>DTG:</b> dolutegravir	<b>PrEP:</b> pre-exposure prophylaxis
<b>ABC:</b> abacavir	<b>EFV:</b> efavirenz	<b>SRA:</b> stringent regulatory approval
<b>API:</b> active pharma. ingredient	<b>FDC:</b> fixed-dosed combination	<b>TAF:</b> tenofovir alafenamide fumarate
<b>ATV/r:</b> atazanavir/ritonavir	<b>LPV/r:</b> lopinavir/ritonavir	<b>TDF:</b> tenofovir disoproxil fumarate
<b>DRV/r:</b> darunavir/ritonavir	<b>PI:</b> protease inhibitor	
	<b>PPPY:</b> per patient per year	

**TLD:** TDF/3TC/DTG (one pill)  
**TLE600:** TDF/3TC/EFV (600mg)  
**TLE400:** TDF/3TC/EFV (400mg)

## Adult ARV Market

### First-Line (1L) Adult Products



#### FDC TLD

DTG-containing FDC expected to improve outcomes and lower costs

Expected SRA approval of **two** generic suppliers

**Late 2017**

#### Inclusion of DTG Guidance



#### Benefits of DTG Relative to EFV

- 1 Higher genetic barrier to resistance
- 2 Fewer side effects
- 3 Lower expected costs
- 4 Faster time to viral suppression

### CHAI-Unitaid Catalytic Procurement of DTG Singles

Under the leadership of Ministries of Health (MoHs) in Kenya, Nigeria and Uganda, CHAI and Unitaid have supported a catalytic procurement of DTG singles to help determine key requirements for national roll-out and to provide a platform for TLD FDC introduction

#### H1 2017 Delivery



#### Key Goals:

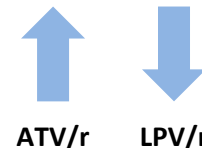
- Understand patient preferences
- Set standards for monitoring toxicity
- Inform areas of potential future trainings
- Identify prescriber knowledge gaps



### 2L ARV Trends



#### 2L PI Use



Preliminary analysis shows ATV/r continued to increase its 2L adult market share from 2015 to 2016

**Reference Pricing (PPPY)**

**ATV/r: \$186\***  
**LPV/r: \$221\***

### Pipeline Adult Products

#### FDC DRV/r

2L PI shown to be superior, or non-inferior, to ATV/r and LPV/r in clinical trials

Expected SRA approval of **two** generic suppliers

**Mid-2018**

#### TAF

Tenofovir pro-drug that may reduce costs due to lower amounts of API needed

Expected SRA approval of **two** generic suppliers

**Mid-2019**

### "Treat All" Guidance

**20+** Surveyed LMICs have adopted WHO-recommended "Treat All" policies

#### Sample Adopters



\*Global Fund PPM Reference Pricing, March 1, 2017; \*\*TLD pricing being negotiated

# Pediatric ARV Market

## LPV/r Oral Pellet Adoption Profile

**12+** LMICs have already placed or will be placing orders for LPV/r oral pellets



### Key Product Information

**Formulation:** LPV/r (40/10mg) oral pellets – 120 caps

**Reference Price:** \$19.20/pack\* **Supplier:** Cipla



## ABC/3TC (120/60mg) Uptake

### Sample Adopters



Kenya



Uganda



Vietnam

**50%**

decrease in pill burden, compared to ABC/3TC (60/30mg) tablets

### Generic Suppliers of ABC/3TC (120/60mg)

**Mylan**

SRA Approved: Q4 2014

**Cipla**

SRA Approved: Q4 2016

## Four Pellet Recommendations

- 1 Prioritize patient populations for adoption (e.g., < 3yrs)
- 2 Establish adoption and implementation plan
- 3 Anticipate 6-9 month lead times
- 4 Monitor adoption in coordination with ARV Procurement Working Group

## Pipeline Pediatric Products

### LPV/r (40/10mg) Granules

Another solid formulation alternative to oral solution

Expected first generic SRA approval

**H1 2018**

### ABC/3TC/LPV/r “4-in-1”

Provides WHO-preferred regimen for patients <3 yrs in one pill

Expected first generic SRA approval

**H2 2018**

The Global Accelerator for Pediatric Formulations (GAPf) and its member organizations continue to play a pivotal role in identifying innovative approaches for fast-track development and introduction of priority formulations



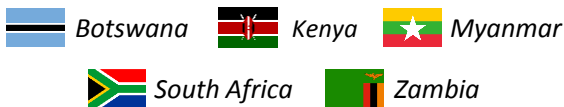
## Prevention

### Updates On Oral PrEP

**10+**

countries have included oral PrEP guidance in national guidelines since South Africa became the first LMIC to introduce oral PrEP in national program in mid-2016

#### Sample LMICs That Have Introduced Oral PrEP Guidance



### Prevention Research Developments

#### Long-acting Injectables (LAIs)

In Dec 2016, HPTN 083, the first phase III trial testing the efficacy of LAI cabotegravir, in doses once every 8 weeks, began with results expected in 2021

#### Implants

In late 2016, the Bill & Melinda Gates Foundation committed up to \$140 million in funding to Intarcia Therapeutics for development of a sub-dermal implant that will dispense PrEP over the course of 6-12 months

#### HIV Vaccine

In Nov 2016, HVTN 702, the first HIV vaccine trial since 2009, launched in South Africa with results expected in 2021

## Diagnostics

### Viral Load Scale-Up

Nearly all LMICs have adopted **routine viral load (VL) testing**. Testing volumes in LMICs **increased by >20%** between 2015 and 2016

#### Shift To Dried Blood Spot (DBS) Testing

LMICs implemented VL using plasma but are scaling up using DBS. In countries that have significantly scaled-up, DBS assumes an average of 60% of total volumes

#### Piloting Point-of-Care (POC) VL

Cameroon, Ethiopia, Kenya, Malawi, Tanzania, and Zimbabwe are piloting POC VL

### Trends In Early Infant Diagnosis (EID)

**5+**

LMICs have adopted **testing at or near birth\***; most are expected to adopt by 2019

\* Each approach is WHO-recommended and expected to accelerate demand for EID testing

**12+**

LMICs recommend **alternative entry points\*** for case finding

**11+**

LMICs are piloting or scaling-up **point-of-care EID\***

### The Future of CD4 Testing

Although CD4 testing remains necessary, volumes are expected to decrease with significant adoption of “Treat All” (see ‘Adult ARV Market’ section) and VL testing for routine monitoring